EXHIBIT D

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E21002 001442

Date: 12/29/2010

Horizon
PO Box 199
Newark, NJ 07101

Patient: Griffin Binko

DOB: 8/16/1988

ID: NVP3HZN08017100

Practice: In Balance Health LLC

Treating Provider: Rick O. Lambert

Enclosed you will find claim forms that are being resubmitted as an appeal for processing.

These claims are not duplicate. The enclosed are:

_____ corrected claims

_____ being refilled to correct an error in processing.

_____ sent with progress notes to establish medical necessity.

X Other: **Spinal Manipulation under anesthesia and all other manipulations under anesthesia or not experimental and investigational. An experimental procedure is very easily addressed in the AMA CPT codebook of reimbursable procedures, in the introduction to that publication. In order for a procedure to be included in the AMA CPT codebook of reimbursable procedures, it must first have undergone clinical validation by being used by same or similar practitioners for the same or similar conditions. It must then go through the review process by an 11-member panel that evaluates the outcomes of the procedure used by same or similar practitioners; the review panel then makes a recommendation that the procedure be included within the proper section of the codebook. This is then part of a recommendation review for publication in the codebook, and the procedure does not appear in this book unless it passes all of these reviews and evaluations**

According to an April 2004 letter from the AMA regarding CPT code 22505, in response to Dr. Daniel West's (an advisory member of the National Academy of MUA Physicians) request for clarification of this procedure, the following is required of the CPT Advisory Committees and the CPT Editorial Panel for CPT publication as a category 1 procedure (which is what 22505 is listed as):

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S21003.001442

"That the service/procedure has received approval from the Food and Drug Administration (FDA) for the specific use of the device or drug;

"That the suggested procedure/service is a distinct service performed by many physicians/practitioners across the United States;

"That the clinical efficacy of the service/procedure is well established and documented in the United States per review literature;

"That the suggested service/procedure is neither a fragmentation of an existing procedure/service nor currently reportable by one or more existing codes; and

"That the suggested service/procedure is not requested as a means to report extraordinary circumstances related to the performance of a procedure/service already having a specific CPT code.

"Therefore, based upon the above information and in response to your specific question, Category 1 codes do not represent experimental or emerging technology"

An experimental procedure is very easily addressed in the AMA CPT codebook of reimbursable procedures, in the introduction to that publication. In order for a procedure to be included in the AMA CPT codebook of reimbursable procedures, it must first have undergone clinical validation by being used by same or similar practitioners for the same or similar conditions. It must then go through the review process by an 11-member panel that evaluates the outcomes of the procedure used by same or similar practitioners; the review panel then makes a recommendation that the procedure be included within the proper section of the codebook. This is then part of a recommendation review for publication in the codebook, and the procedure does not appear in this book unless it passes all of these reviews and evaluations.

Therefore, please reprocess claims in according with the 2004 AMA recommendation regarding Manipulation under Anesthesia accordingly.

Addressing HORIZON BCBS review of this case I offer the following information:

The genesis of MUA over 50 years ago, was involved with the treating and reduction of vertebral fractures and dislocations. However, just like many other medical advances, MUA has since evolved to the application of other spinal joint and extra-spinal joint maladies and conditions. For instance, the shoulder joint is successfully treated with MYA because MUA breaks up fibrous adhesions and restores biomechanics. This in turn reduced patient pain and improved the patient's life. As late as 20-30 years ago, these very same principles have since been assigned to spinal joints as well the pelvic joints. A significant number of authors over the years have documented remarkable outcomes as well as much research and data certainly falls within the parameters for all procedures that

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have gone through this same process as mainstream medicine has adopted new procedures continually throughout history. Today, this process is referred to as evidence-based medicine and is being reintroduced to help continue to develop good procedures that show significant change in patient outcomes assessment, as does the MUA procedure. The medical literature is overflowing with studies that support the efficacy of MUA for the very same conditions with which this patient has been treated.

The following references studies lend further evidence to my assertions, and contradict any consultant with HORIZON BCBS that inappropriately claim that there is "insufficient research evidence of safety and/or efficacy". For instance, use of Table 1, from Haldeman S, Kohlbeck FJ. *Principals and Practice of Chiropractic* 2005, 3rd edition; Chapter 43: 841-860 actually lends evidence to my assertions, in as much as it helps identify many other conditions ascribed to favorable being treated through MUA.

1. A 3-day series of Fibrosis Release Procedures, including Manipulation Under Anesthesia (FRP-MUA), in order to help increase the mobility of the sacroiliac articulations, the lumbosacral articulation, and the lower extremity motions. I have provided substantial scientific evidence below to supports this opinion for this chronic patient, as the best and most appropriate treatment option available to him at this time. This recommendation is also consistent with writing in Chapter 6 of the ACOEM Guidelines, which addresses chronic conditions. I have included these quotations below as they pertain to the application of Fibrosis Release Procedures, including Manipulation Under Anesthesia, for this patient. These Fibrosis Release Procedures, including Manipulation Under Anesthesia, are expected to improve dysfunctional movements, thereby decreasing symptoms and increasing function (page 108). These procedures are expected to further mobilize the restricted articulations (page 115) and obtain and maintain function (page 117) in this patient's lumbopelvic spine. The Mercy guidelines, relied upon by recent case laws regarding chiropractic management of industrial injuries, support the use of FRP-MUA procedures on a case by case basis.

ACOEM, Chapter Six quotations: Page 108, "Chronicity may be reached from one to sex month post injury. The International Association for the Study of Pain has started that three months in the definable time frame, while the American Psychiatric Association uses a six-month limit. The most clinically useful definition might be that, "chronic pain persists beyond the usual course of healing of an acute disease or beyond a reasonable time for an injury to heal."

Page 108, "Dysfunctional movements and patterns such as antalgic gait, abnormal postures, or guarding may contribute to the chronicity of pain. If these movement patterns are normalized, symptoms may be reduced and function increased."

Page 109, "The treatment of chronic pain requires specialized knowledge, substantial time, and access to multi-disciplinary care. Judicious involvement of other professionals, including psychologists, exercise and physical therapists, and other healthcare professionals who an offer extra physical or mental therapy while the physician continues to orchestrate the whole therapeutic process can be helpful."

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Page 115, "Mobilization, even in the face of some residual pain or stiffness, should be encouraged, and it should be increased as the healing process progresses."

Page 115, "Pain medications are typically not useful in the sub-acute and chronic phases, and have been shown to be the most important factor impeding recovery of function in patients referred to pain clinics."

Page 116, "The pain management plan should focus on coping and adaptation in order to restore function."

Page 117, "Pain management focuses on functional restoration. Because return to function is essential to return to health, occupational health professionals are concerned with return to function."

Page 117, "Maintaining function will minimize the stiffness, aches, and atrophy that result from being sedentary. Typically, when function improves, so does perceived pain."

FRP-MUA STUDY

West DT, Matthews, RS, Miller MR, Kent GM, Effective management of spinal pain in one hundred seventy patients evaluated for manipulation under anesthesia. J Manipulative and Physiologic Therapy. 1999: 22. 200-308.

ABSTRACT

Objective: To demonstrate that manipulation under anesthesia (MUA), a conservative treatment modality, is both safe and efficacious in the treatment of both acute and chronic spinal pain disorders in appropriately selected patients. MUA can be safely used to treat pain arising from the cranial, cervical, thoracic, and lumbar spine, as well the sacroiliac and pelvic region.
Setting: An ambulatory surgical center.
Subjects: The treatment group consisted of 177 patients between ages 17 and 65 years. Evaluation followed a treatment algorithm created by the authors as multi-disciplinary approach to patient selection, evaluation, treatment, and time for specialized referral, in consideration of previously published algorithms. Prior forms of treatment, both conservative and surgical in nature, had failed in these patients.
Intervention: Patients underwent three sequential manipulations under intravenous sedation, followed by 4-6 weeks of skilled spinal manipulation and therapeutic modalities.
Outcome Measures: Data regarding changes in Visual Analog Scale (VAS), range of motion, medication needs, and return to work status were used to document progress.

All patients had follow-up for 6 months.
Results: On average, VAS ratings improved by 62.2% in those patients with cervical pain problems. On average, VAS ratings improved by 60.1% in those patients with lumbar pain problems. There was a near-complete reversal in patients out of work before MUA (68.6%)

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and those returning to unrestricted activities at 6 months after MUA (64.6%). There was a 58.4% reduction in the percentage of patients requiring prescription pain medication from the pre-MUA period to 6 months after MUA. Additionally, 24.0% for the treatment group required no medication at 6 months after MUA.

Conclusion: A multi-disciplinary approach to evaluation and treatment, including MUA offers patient benefits above "and beyond what can be obtained through the individual provider working alone. (J Manipulative Physiol Ther 1999: 22:2999-308).

ADDITIONAL FRP-MUA STUDY SUMMARIES

1. Scott Haldeman DC MD PhD in AAOS May 2003, the most recent prospective RCT, World Federation of Chiropractic's 7th Biennial Congress, Medication Assisted Manipulation for Low Back Pain." Department of California. Irvine. Pg 258-259 reported that:

"Medication-assisted manipulation appears to offer patients increased improvement in low back pain and disability when compared to usual chiropractic care." Page 258

***"The relative odds of experimenting a 10-point improvement in pain and disability favored the medication-assisted manipulation group at 3 months and one year."* Page 258**

2. Frank Kohlbeck DC and Scott Haldeman published a literature review of MUA (49 published articles) in 2 (2002); 288-302 Medication-Assisted Spinal Manipulation and concluded the following:

***"Medicine-assisted spinal manipulation therapies have a relatively long history of clinical use and have been reported in the lerature for over 70 years."* Page 288**

"Recent advances in highly titratable and reversible intravenous anesthesia have significantly reduced risks associated with manipulation under anesthesia (MUA), analgesia and sedation, which can now be performed in outpatient surgical centers." Page 289

"There are case reports and case series describing the successful use of MUA other medically assisted manual therapies inpatients..." Page 289

The rationale for the use of MUA is that anesthesia and analgesia help to eliminate or reduce vain and muscle spasm that kinder the effective use of traditional manipulation...to break up joint adhesions and reduce segmental dysfunction to a greater extent that if anesthesia had not been employed." Page 289

"The earliest MUA study... was published in 1930 by the Lancet ... overall 75 percent of patients improved." Page 290
"In a first study by Siehl adBradford published in 1952, 33 percent of the patients demonstrated good {syptom-free} results." Page 294

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"Stehl's follow-up study; 96 percent reports successful (good or fair) outcomes.

"Mesner's study includes 205 patients...51 percent of the patients reported satisfactory results." **Page 294**

"In Chrisman's study, 83 percent of the subjects reported good or excellent results after a 3 year follow-up." **Page 294**

"In Morey's J 973 review ,,-treating physician reported excellent or good results in 85 percent of the cases." **Page 294**

"In a study published in 1986 by Krumhansel and Nowacek...outcomes were reported as 25 percent 'cured'. 50 percent 'much improved' and 20 percent 'better', Page 294

"In a 1990 article by Mennell...30 percent with symptoms cured, 35 percent with marked improvement, 29 percent with moderate improvement..."Page 294

In a recent case series by West* etal...*VAS scores improved 4.6points for cervical pain and 4.31 points for lumbar pain. Decrease in time off work and less use of prescription pain medication were also reduced." Page 294 (This is the ONLY article reviewed by ACOEM and somehow led to their conclusion of "not recommended)."

"Current procedures more commonly use more commonly specific, short lever, high velocity low amplitude thrusts characteristics of chiropractic and modern osteopathic adjustive techniques in addition to mobilization." Page 294

"A typical MUA procedure involves placing the patient in a twilight anesthesia by a board certified anesthesiologist while the clinician with the aid of a skilled assistant provides specific mobilization and manipulation techniques to the affected joints and spinal regions." Page 294

"Current guidelines recommended the presence of a primary physician and assisting physician who have both undergone adequate training: in MUA procedures. An Assistant is necessary to position the patient and stabilize the sedated patient." Page 295

"We have been unable to find any report of complications using more modern osteopathic and chiropractic techniques or as a result of the use of anesthesia." **Page 297**

"If a clinician recommends MUA, it would be difficult to deny the use of medication-assisted manipulation or fail to reimburse for it."

"The literature (a PubMed search from1966) consists primarily of case reports and case series with two randomized controlled trials and one cohort study."

Daniel West et al reported in a JMPT 1999-22 5 study titled "Effective Management of Spinal Pain in 177 Patients Evaluation for MUA"

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"Vas rating improved by 62.2 percent in those patients with cervical pain problems and 60.1 percent in those patients with lumbar pain problems. There was a near complete reversal (68 percent) in patient out of work before MUA, and those returning to unrestricted activities at 6 months after MUA totaled 64.1 percent. There was a 58.4 percent reduction in the percentage of patients requiring prescription pain medication from the pre-MUA period to 6 months after MUA. Additionally, 24 percent of the treatment group required no medication at 6 months after MUA." **Page 299**

"The addition of anesthetic allows for the benefits of manipulation to be shared with those patients who cannot toleration manual techniques because of pain response, spasm, muscle contractures, and guarding." **Page 300**

"MUA has been used successfully in treating those patients unresponsive to acute and chronic musculoskeletal conditions for years." **Page 300**

"Only highly skilled, graduate practitioners who have been trained in structural diagnosis and manipulative treatments should be performing these procedures." **Page 300**

"All patients with diagnosed spinal conditionals received treatments in the area of primary diagnosis, as well as the areas superior and inferior. This is due to the anatomy of the ligamentous, tendonous, and muscular origins and insertions (i.e. if the lumbar spine is the primary site of injury, the treatment areas were thoracic, lumbar, and pelvic)." **Page 303**

"Performance of the MUA procedure requires a certified MUA first assistant for stabilized and patient positioning, as well as direct ancillary treatment. Page 304
'We believe we have shown that this treatment program is safe and efficacious in comparison with other treatment options.' Page 307

4. Palmieri et al. October 2002. Chronic LBP: A study of the effects of MUA. JMPT Oct 2001:25(8):E81

Demontrated clinical efficacy of MUA performed in a series of three consecutive procedures. The average Numerica Pain Scale scores in the MUA group decreased by 50 percent, and the Roland-Morris Questionnaire scores decreased by 51 percent compared to a controlled group..

"Existing methods for managing non pathologic chronic back pain include patient education, back schools, spinal injections, medications, physical therapy, exercise and rehabilitation, acupuncture, spinal mobilization and manipulation, behavioral modification, and work and lifestyle activity modification. The MUA procedure is typically performed on patients who have received some or all of these treatments without favorable results." **Page 2**

Siehl D. Manipulation of the Spine under General Anesthesia. J Am Osteopath Assoc. June 193: 62;35-41. "...the reposition under anesthesia is harmless and presents absolutely an acknowledged and trustworthy procedure in treatment." Page 36

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"However, I believe that manipulation under anesthesia might be well be the ideal treatment in many cases of acute low back and neck problems." Page 37

"Of the patients having merely myofibrositis or a similar pathologic state, 96.3 percent were improved (good to fair results), making manipulation (under anesthesia) worth while." Page 38

"It becomes evident from the review of these cases that manipulation of the spine under general anesthesia is a valuable procedure, but the cases must be specifically selected". Page 39

"The steady spasm and the consequent postural defects combine with local pain, tetalgia, disturbances of the sympathetic nervous system, insomnia, and fatigue to form a vicious circle which magnifies the disability. Therefore, in an attempt to break up this vicious circle, manipulation of various types is carried out through the spinal areas. This can be applied more effectively in many cases with the patient under general anesthesia. Page 39

"A high percentage of good results can be obtained with careful evaluation and selection of cases." Page 39

6. Davis CG. DC. Fernandez CA. MD. Do Motta MA. DC. Manipulation of the Low Back Under General Anesthesia: Case Studies and Discussion. J of Neuromusculokeletal System. Fall 1993; 1(3):12~134.

"Following this course of treatments, there was marked improvement in pain, with improvement in this orthopedic and neurologic exam. Medication use was decreases in functional capacity increased." Page 126

"Failed back surgery syndrome is a common indication for MUA." Page 126

"MUA was presented to the patient as an option for attempting to improve pain control and functioning. The procedure resulted in marked symptomatic improvement immediately after the MUA. Additionally, functional ability improved in these patients for whom physicians had expressed little hope of recovery of normal function." Page 129

"The cross-links bind collagen fibers so that movement is restricted. When subjected to a high-velocity thrust, these cross-links may be disrupted without a resultant inflammatory reaction that would occur if the collagen fibers were tom." Page 132

"The two patients in this case report had prolonged symptoms and each had a number of back surgeries with radiographically identified postoperative scarring." Page 132

"The MUA procedures in these cases have had longer lasting results than previous surgeries, nerve blocks, or medications." Page 132

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"Reports of manipulation under anesthesia have gone back as far as 1930 when Riches reported successful treatment of 87 percent of his patients with chronic sciatica, and 92 percent with chronic sacroiliac strain with manipulation under anesthesia." Page 132

"Many of the techniques require at least two operators, since control of the weight of the patient's body and of the extremities rest entirely with the operators when the patient is under general anesthesia. This is particularly important with treatment directed at the lumbar spine and pelvis." Page 133

"The assistant operator is needed for the positioning and stabilization of the patient and to assist in manipulations." Page 133

"Care must be taken not to manipulate too vigorously under anesthesia. Instead of trying to achieve full range of motion in one manipulation it is often better to manipulate more gently on two or more occasions." Page 133

Mennell has stated that it is no more irrational to use anesthesia to provide relaxation and to avoid pain in joint manipulation than it is to use anesthesia for the reduction of fractures and dislocation or extracting a tooth." Page 133

"Both patients also regarded their functionality capacity as being much improved." Page 133

"With patients who have undergone surgery only to have the pain return due to scar tissue and fibrosis, MUA may be beneficial." Page 134

7. Mennell J MCM, MD. The Validation of the Diagnosis Joint Dysfunction in the Synovial Joints of the Cervical Spine. JMPT Jan 1990; 13 (1):7-12

"I use it (MUA) to obtain pure relaxation, for pain relief and sometimes for expedience – never so that I may use more force or any difference technique." Page 11

"My manipulative techniques are exactly the same with the patient aware or asleep. It is interesting that when asleep, the patient's restricted joint movement (amount of loss function) is exactly the same as when they are awake." Page 11

"When a patient is anesthetized, the therapeutic techniques used are exactly the same though they are performed even more gently." Page 11

8. Grenman PE DO. Manipulation with the patient under anesthesia. JAOA Sept. 1992;92(9): 1159-1170.

"Safety and effectiveness are favored by appropriate selection of patients, knowledge of indications and contra indications, suitable anesthetic, and services of a qualified physician trained in structural diagnosis and manipulative technique." Page 1159

The patient was symptom-free for the succeeding 18 months, ...Page 1160

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"The patient's condition was greatly improved 24 hours after undergoing manipulation under anesthesia, and she was symptom-free within 10 days. No subsequent sequelae occurred for 18 months. Minor recurrence then responded quickly to more usual form of manual medicine." **Page 1160**

"The purpose of the anesthesia is to obliterate the pain and muscle spasm that has prevented other forms of conservative manual medicine care from being effective." **Page 1167**

"Additionally, an experience team can accomplish the procedure more quickly and save anesthesia time. Many of the techniques recommended...require a minimum of two operators." **Page 1167**

9. Herzog J, DC. Use of Cervical Spine Manipulation Under Anesthesia for Management of Cervical Disk Herniation, Cervical Radiculopathy and Associated Cervicogenic Headache Syndrome. JMPT Mar/Apr 1999;22(3): 166-70.

"The patient had immediate relief after the first procedure. Her neck and arm were reported to be 50 percent better after the first trial, and her headaches were better by 80 percent after the third trial. Four months after the last procedure the patient reported 95 percent improvement in her overall condition." **Page 166**

"The generally accepted rationale for how MUA works is based on solid scientific data relating to muscle and joint physiology. **Page 166**

"Siehl and Claybourne have documented the validity of MUA as a procedure us; in treating musculoskeletal disorders when restriction of the joint, joint capsule surrounding musculature has taken place as a result of the formation of fibrous adhesions." **Page 166**

"She returned to work and maintained the improvement three months later. **Page 168**

"The post-MUA therapy continues for a total of 6 to 8 weeks. At that time the patient will have achieved a maximum therapeutic benefit and be discharged. Rehabilitation and strengthening of the supporting tissues will help maintain the effects of the alteration of the fibrous adhesions that have occurred with the MUA." **Page 169**

"Regardless, it seems to appear that MUA has a positive effect on certain types I: conditions that have been unresponsive to traditional therapeutic approaches." **Page 169**

"Significant increase in overall muscle flexibility and spinal range of motion was realized after each treatment. The rationale for MUA use is to control and alter fibrous adhesions that are a result of the inflammatory circle." **Page 170**
"MUA has been shown to be of benefit in a case of cervical disk herniation with cervical radiculopathy and cervicogenic headache syndrome." **Page 170**

10. Rumney IC, DO. Manipulation of the Spine and Appendages under Anesthesia: An evaluation. JOAO. Nov. 1968; 6875-85

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"Tospon reports that, in treating over 200 cases of ligamentous strain of the neck due to auto accident, early manipulation under anesthesia (second or third week after the accident) lessened the morbidity and hastened the recovery." Page 76

"In 1955 Mensore reported good results in 64 percent of private patients and 45 percent of patients whose disability was caused by industrial accidents. After 20 years experience and treatment of more than 600 patients with manipulations of the back under anesthesia he has had sufficiently results to continue with this procedure." Page 76

"When the condition advanced to fibrosis one is faced with prolonged program, and it is at this point that manipulation therapy under anesthesia is most frequently indicated." Page 77

"Even after the manipulative procedures break up the fibrosis, one must institute an adequate program of physical therapy and exercise. If one does not prevent, or lessen, the formation of fibrous tissue, the patient's original problem will recur." Page 77

"Only physicians who are well trained in the art of manipulative therapy should employ anesthesia for such procedures." Page 85

11. Samuel Turek MD orthopedic surgeon, reports in his textbook, Principles and Applications of Othorpedics.
"good to excellent results" can be expected in 50 percent of patients with acute herniated nucleus pulposis with MUA.

12. Thomas Dorman, MD, Orthopedist, Diagnosis Techniques in Orthopedic Medicine.

"MUA is recommended when the patient has failed at conservative in-office care.

13. Robert Mensor, MD, orthopedic surgeon

Conducted a large clinical trial of over 600 patients with EMG verified radiculopathy and found that 83 percent responded well to MUA.

14. Christman OD, MD et al. A Stud of the Results Following Ratatory Manipulation in the Lumbar IVD Syndrome. J Bone and Joint Surgery. 1984 Apr; 46-A(3)

Reported that 51 percent of patients with unrelieved symptoms after conservative care has good to excellent results even three years after MUA.

The most recent publication about MUA is summarized in the abstract that follows:

MANIPULATION UNDER ANESTHESIA:
A REPORT OF FOUR CASES

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Edward Cremata, DC,a Stephen Collins, DC, b William Clauson, MD, c Alan B. Solinger, PhD, d and Edward S. Roberts, DCe

ABSTRACT

Objective: To report the results of manipulation under anesthesia (MUA) for 4 patients with chronic spinal, sacroiliac, and/or pelvic and low back pain.

Methods: The treatment group was arbitrarily selected from the chiropractor's patient base who received the MUA protocol along with a follow-up in-office articular and myofascial release program that mimics the MUA procedures. The chiropractic adjustments and articular and myofascial release procedures were performed in a chiropractic office. The MUA procedures were performed in an outpatient ambulatory surgical center. Patients with chronic pain who has not adequately responded to conservative medical and/or a reasonable trial (4 months minimum) of chiropractic adjustments, and has no contradictions to anesthesia or adjustments, were selected. The 4 patients went through 3 consecutive days of MUA followed by an 8-week protocol of the same procedures plus physiotherapy in-office without anesthesia. Data included pre- and post-MUA passive ranged of motion, changes in the visual analog scale, and neurologic and orthopedic examination findings. The patients had followed-up varying from 9 to 18 months.

Results: Increases in passive ranges of motion, decreases in the visual analog scale rating, and diminishment of subsequent visit frequency were seen in each of the patients.

Conclusion: Manipulation under anesthesia was an effective approach to restoring articular and myofascial movements for these 4 patients who did not adequately respond to either medical and/or in-office conservative chiropractic adjustments or adjunctive techniques.

(J Manipulative Physiol There 2005; 28-526-533)

Key Indexing Terms: Manipulation, Chiropractic; Anesthesia; Manipulation, Spinal; Spine; Sacroiliac Joint; Low Back Pain

2. In order to maximize the benefit of the Fibrosis Release Procedure, including Manipulation Under Anesthesia x3, this patient should then undergo a 2-month rehabilitation program, following strict post-MUA protocols in order to maximize the patient's benefit from the FRP-MUA procedures. This two months of post procedure rehabilitation should include the reproduction of the manipulation, traction, myofascial release, and mobilization procedures provided while the patient is sedated during the FRP MUA procedures, and should include further functional restoration/work conditioning as recommended by numerous guidelines, including the ACOEM Guidelines, and to include a

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formal program that addresses proprioception, flexibility, strength, and aerobic function. The patient should then be monitored for an additional 4 weeks, with reducing treatment frequency, at which point the patient can likely be considered permanent and stationary (Total 12 weeks of treatment being recommended). It is my hope that these procedures will improve the patient's condition sufficiently so that the patient can return to the previous occupation upon being declared permanent and stationary and within 90 days of having the FRP-MUA procedures. A return to modified work should be attempted during the rehabilitation process, after the FRP-MUA procedures, and based on my experience, a likely time to return the patient to modified duties would be approximately 1 month after the patient undergoes these procedures. It is hoped that at 3 months after the procedures, the patient can be considered permanent and stationary and be returned to usual and customary work without modification.

3. The patient should continue with the physiatrist or primary care doctor in order to manage any necessary pain medications while undergoing the future treatment recommended over a 90-day period. It is quite likely that during these procedures and aggressive rehabilitation that the patient's symptoms would increase and decrease, depending on activities and the response to the procedures, and that the patient should therefore have the option of obtaining medication and appropriate management from one of the aforementioned medical physicians.

I tryst that the aforementioned information will allow you to make a just determination of the procedures that were rendered to Daniel Zanias. His MUA treatments of 9/29/08, 9/30/08 and 10/1/08 were warranted, appropriate, beneficial and medically necessary for the treatment of his condition. Please contact me should you require any additional information or more references.

Second level appeal.

Thank you for your prompt attention.

Sincerely,

Kelly J. Langschultz
Billing Specialist

S21005.001442

Precision Billing™
& CONSULTING SERVICES, LLC

12,29,2010

VIA CERTIFIED MAIL/RRR

Horizon
PO Box 199
Newark NJ 07101

Re: Request for Experimental Procedure Policies/Plan Documents
Patient Name: Griffin Binko
Benefit Plan: employer
Dates of Service: 07|08|10, 7|9|10, 7|10|10

Dear Sir/Madam:

Please accept this letter as notification of our authorization as representative to act on behalf of Griffin Binko in the above-referenced adverse benefit determinations. Attached is a copy of the authorization for your records.

This letter is also a request for additional information. It is our understanding that the above-referenced claim was denied pursuant to a plan exclusion related to experimental/investigational treatments. The denial/explanation of benefits, however, did not give adequate information to establish the accuracy of this decision.

Thus, we hereby request the following information to support the denial of benefits for this treatment: (1) a copy of the experimental/investigation treatment limitation in the plan or policy as well as any related definitions; (2) if internal clinical guidelines were utilized and/or are applicable, please provide a copy of each such clinical guidelines as well as the name and credentials of the medical professional who reviewed the treatment records; (3) an outline of the specific records reviewed and a description of any records which would be necessary in order to approve the treatment; and (4) copies of any expert medical opinions reviewed by your company in regards to treatment of this nature and its efficacy so that the treating provider may respond to its applicability to this particular patient's condition.

As you are likely aware, both state and federal disclosure laws as well as plan terms may be applicable and require the release of detailed information to substantiate

an adverse benefit determination. If you believe this request does not fall under said disclosure requirements, please provide a written explanation.

Finally, we hereby request on behalf of our patients a copy of the Summary Plan Description ("SPD") required to be maintained by the Plan and provided upon request to the Plan Beneficiary under ERISA. Please note, an enrollee/beneficiary may file suit against a Plan Administrator who fails to comply with the enrollee's/beneficiary's request for a copy of the latest SPD. Indeed, Section 502(a)(1)(A) of ERISA indicates the Plan Administrator has thirty (30) days to provide the SPD to the enrollee/beneficiary. The Plan Administrator may be held liable for up to $110.00 per day for each day it fails to provide the SPD to the enrollee/beneficiary.

Thank you for your cooperation. We look forward to receiving the requested materials and pursuing the appeal of the adverse benefit determinations.

Respectfully yours,

Kelly J. Langschultz
Director

521003.001442

In-Balance Health LLC
305 W Grand Avenue
Montvale, NJ 07645

December 29, 2010

Horizon Blue Cross Blue Shield of New Jersey
PO Box 199
Newark, NJ 07101

RE: **Griffin Binko**
Member ID: **NVP3HZN08017100**
Plan: **PPO**
DOS: **07/08/10, 07/09/10, 07/10/10**
Physician: **In Balance Health**
Claim: **20101970218000/multi**

Letter of Appeal

Please be informed that the decision of non-payment of the services provided for **Griffin Binko** at Montvale Surgical Center are being appealed for the following reasons:

1. Horizon Blue Cross Blue Shield claims that CPT code 22505 is investigational

   The AMA-CPT guidelines for establishing treatment procedure codes are very strict and precise. The codes are not given to experimental procedures or procedures that remain under investigation. The fact that CPT codes exist for the procedures indicates that the procedures are not unsafe, unproven, experimental or investigational. Annexed hereto is a copy of "The Whole Truth about MUA" written by Dr. Robert Gordon fully describing the steps in which a procedure is evaluated before given a CPT code. The article also clarifies the worn out argument that MUA warrants further investigation. Two researchers concluded that MUA showed a definite clinical benefit and that they would like to see more and better deigned studies on MUA. This is true for every good medical procedure and progress on our profession.
2. The specific services denied by **BCBS** were manipulation of the **pelvis and lumbar spine** under anesthesia. In review of the **HCFA-1500** submitted by In-

Balance Health we see that the diagnosis for **Mr. Griffin Binko is acquired pelvic obliquity with contracture of the pelvis and thigh. The diagnosis for the lumbar spine was discopathy and radiculopathy.** Looking at the admitting consultation note prepared by **Dr. Lambert** on **06-30-2010** we see that the patient had multiple positive findings supporting the diagnosis given. MRI and electro/neuro diagnostic tests support the diagnosis of multiple discopathies with radiculopathy. The chronicity of **12 months** as pointed out by Dr. Lambert's note, has caused the **acquired deformity of the pelvis.**

Regarding the clinical support of the diagnosis for multiple discopathies with radiculopathy, BCBS does not contest the diagnosis. They only claim that MUA of the spine is investigational. Nevertheless, there does not exist guidelines by which MUA is practiced and patients are selected for MUA of the lumbar spine. These same guidelines are acknowledged by The National Arbitration Forum for deciding the appropriateness of an MUA when disputed by PIP carriers. Also CMS- Medicare has a fee schedule for MUA of the lumbar spine. New Jersey recently adopted a fee schedule for MUA including lumbar Spine, for PIP cases. BCBS is contradicting CMS- Medicare and other nationally recognized standard of care committees when they claim that MUA of the lumbar spine is investigational. Attached you will find a copy of Dr. Francis' "Overview" which clearly sites several studies that support the efficacy of MUA for lumbar discopathy with radiculopathy.

3. BCBS listed ICD codes that they deemed MUA was proven for. On that list was the code 839.42 which is an ill defined dislocation or subluxation of the pelvis. This code is usually used for trauma cases. With regard to **Griffin Binko**, it is more appropriate from a clinical reporting perspective to use 738.6 which indicates the twisting and contracture of the pelvis over a period of time. MUA is directly indicated for both codes: one indicates acute and the other indicates chronic luxation/subluxation of the pelvis. **Dr. Lambert** supports his diagnosis with significant limitations in range of motion and positive orthopedic tests including SLR, Iliac compression SI Rocking, Trendelenburg, and Gaenselen.

Clinical Justification for Manipulation under Anesthesia:
By the National Academy of MUA Physicians

- The patient has responded favorably to conservative, non invasive chiropractic and medical treatments, but continues to experience intractable pain and/or biomechanical dysfunction.
- Sufficient care has been rendered prior to recommending MUA (standard is 2-6 weeks)

- Manipulative procedures have been utilized in the clinical setting during the 2-6 weeks period prior to recommending the MUA.
- The patient's level of reduced pain interferes with lifestyle. (sleep, daily functional activities, work habits, etc.)
- When medical pain management parameters for immediate acute care protocols are met and if it is recommended by the medical pain management specialist, the MUA procedure can be used in conjunction with medical pain management for treatment of acute pain.
- Diagnosed conditions must fall within the recognized categories of conditions responsive to MUA. The following disorders are classified as acceptable conditions for utilization of manipulation of anesthesia:
- Patients whereby manipulation of the spine or other articulations is the treatment of choice, however, the patient's pain threshold inhibits the effectiveness of conservative manipulation.
- Patients whereby manipulation of the spine or other articulations is the treatment of choice, however, due to the involuntary contraction of the supporting tissues (splinting mechanism), patient treatment is delayed or may be prolonged.
- Patients whereby manipulation of the spine or other articulations is the treatment of choice, however, due to the extent of the injury mechanism, conservative manipulation has been minimally effective in 2-6 weeks of care and a greater degree of movement of the affected joint(s) is needed.
- Patients whereby manipulation of the spine or other articulation is the treatment of choice by the physician, however, due to the chronicity of the problem and/or the fibrous tissue adhesions present, conservative manipulation is incomplete.
- When the patient is considered for spinal disc surgery, MUA is an alternative and/or an interim treatment and may be used as a therapeutic and/or diagnostic tool in the overall consideration of the patient's condition.

Comment: In review of the Consultation Note from **Rick Lambert, MD** and the supporting MRI and EMG/NCV findings, **Griffin Binko** was properly selected for MUA of the **pelvis and lumbar spine** according to the NAMUAP.

Summary

- BCBS denied payment for MUA services because BCBS concluded that MUA was not the national standard of care for the diagnosis given. Yet, national standards do exist that accept MUA as the treatment of choice for select patients that fit the criteria. **Griffin Binko** fits the criteria.
- BCBS claimed that MUA is experimental and investigational. Yet, there exists AMA-CPT codes that indicate that MUA is not investigational or experimental.

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Co-existing are nationally accepted criteria for practicing MUA on selected patients. These guidelines are used by the National Arbitration Forum.

- New Jersey has accepted a fee schedule for paying MUA services for PIP cases.
- CMS has a fee schedule for MUA.
- Manipulation Under Anesthesia has been utilized in manual medicine for more than 60 years. It is safe and extremely effective for the reduction of fibroblastic accumulation in and around joints and the associated musculature. It reduces and relieves contractures. Almost one year post procedure, **Griffin Binko** remains with a sustained benefit from his MUA procedure.
- The procedures performed for **Griffin Binko** at **Montvale Surgical Center** in **July of 2010** should be paid promptly and without prejudice.

Sincerely,

Kelly J. Langschultz

On behalf of Rick Lambert, MD

Dynamic Chiropractic
September 14, 2005, Volume 23, Issue 19

The Whole Truth About Manipulation Under Anesthesia (MUA)

(What Is Being Newly Referred to as Medication-Assisted Manipulation)

by Robert C. Gordon, DC, DAAPM

It has been some time since I have addressed this topic in this publication. Part of the reason is that I have been leting a textbook on MUA, and the other reason is that there have been many changes as far as written material and :ols with regard to the MUA procedures. These changes have come about because MUA has taken on new interest i :ld of both chiropractic and osteopathy in the last few years, and in the field of pain management in general.

I have mentioned previously that MUA will continue to be a very productive alternative in the field of pain gement and that despite the arguments that the insurance carriers continue to mount against MUA, it is here to stay. urpose of this article is to present information as a rebuttal to what the insurance world has been trying to do: nce the health care arena that MUA is investigational or experimental, and therefore should not be reimbursable. Th h a tired, old argument that it is hardly worth the time to discuss. But because it is constantly referred to in the denic ome of the more prominent insurance carriers use, it is time to address these concerns.

There are several points that seem to constantly be used by insurance carriers to deny claims for manipulation under nesia, or what is now commonly referred to as fibrosis release procedures using medication-assisted manipulation nonitored anesthesia care (MAC). We use this terminology to better describe what is actually occurring during the dure, which is listed in the AMA CPT codebook of reimbursable procedures as 22505, "manipulation of the spine ing anesthesia, any area," considered a category 1 CPT coded procedure. The points or arguments that I would like ss regarding this procedure are the following:

1. Is MUA an experimental/investigational procedure? In Frank Kohlbeck and Scott Haldeman's 2002 article in *pine Journal*,[1] they state that the MUA procedure has been used for more than 70 years. They mention that much of view of the literature indicates that anecdotal information is more prevalent than true randomized controlled studies at the field of medication-assisted manipulation needs more investigation. I believe that this is very true, and that re absolutely right. But the statement, made by two prominent researchers, is being misrepresented. What was said at more investigation was necessary, just like any procedure should be continuously researched; and that as with ar procedure, as more research is accomplished, more is understood about what is occurring, when the results have bee matic as the results using the MUA technique. They did not say the procedure is investigational or experimental. investigation into a procedure for a better understanding of outcomes is not the same as an investigational procedur as no historical track record. Even though much of the clinical record for the MUA procedure has been passed dow nical case-study form, there is considerable historical evidence of positive patient response.

What is an experimental procedure, and when does it become acceptable in the health care arena as a non- imental procedure? This is very easily addressed in the AMA CPT codebook of reimbursable procedures, in the luction to that publication.[2] In order for a procedure to be included in the AMA CPT codebook of reimbursable dures, it must first have undergone clinical validation by being used by same or similar practitioners for the same or ir conditions. It must then go through the review process by an 11-member panel that evaluates the outcomes of the

dure used by same or similar practitioners: the review panel then makes a recommendation that the procedure be led within the proper section of the codebook. This is then part of a recommendation review for publication in the ook, and the procedure does not appear in this book unless it passes all of these reviews and evaluations.

According to an April 2004 letter from the AMA regarding CPT code 22505, in response to Dr. Daniel West's (an ory member of the National Academy of MUA Physicians) request for clarification of this procedure, the following ed of the CPT Advisory Committees and the CPT Editorial Panel for CPT publication as a category 1 procedure h is what 22505 is listed as):

"That the service/procedure has received approval from the Food and Drug Administration (FDA) for the specific of the device or drug;

"That the suggested procedure/service is a distinct service performed by many physicians/practitioners across the d States;

"That the clinical efficacy of the service/procedure is well established and documented in the United States per v literature;

"That the suggested service/procedure is neither a fragmentation of an existing procedure/service nor currently able by one or more existing codes; and

"That the suggested service/procedure is not requested as a means to report extraordinary circumstances related to erformance of a procedure/service already having a specific CPT code.

"Therefore, based upon the above information and in response to your specific question, Category 1 codes do not ient experimental or emerging technology."[3]

Apparently, the MUA procedure passed all of the required reviews, because it has a CPT code. That code, 22505, is in an area of the CPT codebook that describes procedures involving the spine and the use of an anesthesia with the The book does not indicate that the procedure is used with any specific kind or type of anesthesia, but describes ipulation of the spine requiring anesthesia, any area." It also is described as manipulation of the spine. It does not to mobilizing the spine after fracture or dislocation; it specifically relates to "manipulation." The codes that are used this code in the CPT code-book specifically describe fracture of the spine methods, which may or may not involve ulation while "setting or relocating" fractured spinal segments.

CPT code 22505 was placed in this codebook when the procedure was more prominent in the osteopathic and pedic arenas. It was used to describe more advanced mobilizing, manipulating, and adjusting of the spine and nding holding elements while the patient is under the influence of anesthesia. Today, the more skilled practitioners iropractic and osteopathic professions, using this technique more frequently and with the more advanced forms of nesia, are better able to accomplish what we want to accomplish by using MAC (monitored anesthesia care). This not change the fact that this is the proper code for this procedure. CPT code 22505 is used as a category 1 code in th ook of reimbursable procedures and is therefore not an investigational or experimental procedure.2 This question o imental/investigational concerns has been brought before the CPT codebook review panel: it related that the code is as a category 1 code and as such, has had the proper follow-up in clinical justification and therefore, as stated abov considered experimental.

2. Is MUA a logical medical alternative in the normal progression of health care delivery for musculoskeletal pain and/or injury? Despite what some would think, both in the chiropractic arena and the al arena, MUA has taken its rightful place in the natural regime of pain management. In most of the cases that have completed, the patients have chronic, recurrent neuromusculoskeletal problems that have been under care in various . for an average of two to three months. Most cases have already undergone injection therapy. Most have exhausted al therapy regimes with minimal results, at best. Many have been surgical failures, even with a minimally invasive dure. And most have had comprehensive diagnostic workups that have been indecisive in terms of the etiology of th it's complaint. MUA patients experience true "last resort" propensities because other therapies have just not worked. mber, MUA cases are selected based on specific parameters, one of which is response to manual therapy, even if or nal.

3. Has enough research in this field been completed to justify its use as compared to other more prominent dures that are used and reimbursed routinely (e.g., intradiscal electrothermal therapy [IDET], minimally ive disc surgery), but like MUA, still need more research? There is never "enough" research for prominent nent modalities, and the continuously expanding volume of knowledge about procedures is always at the core of cal everyday use. But the use of modalities that are showing successful results should not be hampered by unfounde l or antiquated opinions based on a particular person, company or group that has not taken the time to fully igate outcomes. Again, I quote from the literature review completed for the North American Spine Society's *The Journal*, wherein Kohlbeck and Haldeman state:

"If a clinician recommends or offers, and a payor reimburses, surgery, injections, epidurals and certain physical py approaches to patients without requiring substantial proof of the effectiveness and safety, then it would be difficu ny the use of medication-assisted manipulation or fail to reimburse for it."[1]

This article is constantly quoted by insurance carriers in piecemeal fashion to help deny claims for MUA, even h the context of the article was not completely used. The authors continue on as a conclusion for their review by g: "If on the other hand a clinician or payor rejects all surgery that does not have a body of controlled clinical trials rting its use and refuses to offer patients or pay for most injection and physical therapy procedures that have limitec research support, then it would be reasonable to reject medication-assisted manipulation until such research is carrie ld published." This certainly would be the case if all of the modalities that are used to treat the general public today put under the same scrutiny. However, the authors conclude that since this is not the case: "It would seem sonable to hold medication-assisted manipulation to a higher standard of scientific rigor than that required of other nent approaches."[1]

4. What is the focus of the future of this procedure and how will it become more mainstream in the health ca ery field, especially in the field of pain management, in the next few years? Every year, hundreds of cases are treated by using this modality. As has been customary in the past, much of what is being accomplished is being los nical record instead of documentary research. It is hoped that this is changing rapidly with the advent of new researc s, and with the countless number of patients responding so well to this modality, the future of MUA has to be in the ve documentation that will be recorded in our scientific journals. But in the same context, continued use of MUA is ly way we will see the validity of this procedure. And just like other modalities that have been standards of care for ny years, MUA will take its rightful place alongside these treatment options, not because it is a new fad or a billable dure that generates additional revenue, but because it improves the lives of countless patients with conditions that nd best to the procedure.

References

1. Kohlbeck F, Haldeman S. Medication-assisted spinal manipulation. *The Spine Journal* 2002: 288-302.
2. AMA CPT codebook.
3. Letter from the AMA CPT Code Panel to Dr. Daniel West, April 2004.

Robert C. Gordon, DC, DAAPM
nury, North Carolina

AN OVERVIEW OF MANIPULATION UNDER ANESTHESIA (M.U.A.)

By Robert S. Francis, D.C., Associate Professor
Course Director, Division of Post Graduate Studies, TCC

The first certification course in M.U.A. for chiropractors was developed in the mid 1980's by Dr. Robert Francis, while Dean of Clinical Sciences at Texas Chiropractic College. A variety of standards for M.U.A. have been taught since by non-academic proprietary organizations over the last 15 years. M.U.A. has been utilized in manual medicine for over 60 years. Increased participation of chiropractors on hospital medical staffs and with medical physicians has made both the facilities and training more available for performing and credentialing this procedure.

Specific protocol for the procedure has been developed by academic institutions and national and international organizations towards an effort to recognize training programs and clinical outcomes that establish a safe and effective means of implementing this procedure across the country in appropriate hospital and ambulatory surgical settings.

Most recently, the international M.U.A. Academy of Physicians was organized to provide an avenue for the dissemination of valid and authoritative data base of current research and new scientific developments in the field of M.U.A. for physicians dealing with chronic difficult cases through efforts to develop evidence based principles for M.U.A. clinical application and practice.

Continuing education and international conferences are designed to accomplish, implement, fulfill and discharge the purpose and intent of this mission. The objectives of these continuing education conferences are to present by an international and interdisciplinary faculty, a state of the art review of the present knowledge in the field of non-operative care, interventional diagnostic and therapeutic procedures and other relevant treatment modalities affecting the spine.

It has been well documented in the medical literature for over forty years that chronic unresolved non-surgical musculoskeletal conditions respond well to Manipulation Under Anesthesia. M.U.A. is a procedure designed to restore the lost range of motion of the spine and extremities and to reduce the scar tissue. This results in more flexibility and visco-elasticity of the spinal musculature thereby increasing the functional capacity of the patient. M.U.A. is a procedure utilized in selective patient population which has been recalcitrant to an adequate trial of conservative care in the office setting.

M.U.A. requires the use of non-paralyzing anesthesia (patients continue to breathe on their own during the procedure) towards an effort to provide relaxed skeletal musculature enabling the manipulator to reduce fibroblastic proliferative tissue and restore articular motion without patient guarding and pain. Generally, pre-op medications include Versed and Fentanyl with Propofol used in the operating room without intubation to accomplish flaccid muscular relaxation.

This patient is an outpatient procedure and is performed in an appropriate setting providing access to monitoring and resuscitation equipment in a facility certified or licensed to provide operative environment which can provide transfer capability to inpatient care.

It is recommended that an assistant who is certified in the procedure be present to assist in the performance of M.U.A. It is essential that the assistant be knowledgeable in the biomechanics and pathomechanics of the condition being treated towards an effort to assist proper positioning before and during the manipulative procedures performed by the primary physician. Many manipulative procedures under anesthesia are performed in tandem by the manipulator and assistant.

Because of the extensive clinical data on the efficacy of M.U.A., Manipulation Under Anesthesia has been endorsed and included in the American Medical Association CPT Code Publication since 1971. The CPT code for Spinal M.U.A. is 22505. There are other CPT codes for Appendicular Manipulation Under Anesthesia. Below listed are references and partial abstracts outlining the efficacy of M.U.A.

In October, 2002, Palmieri et al. demonstrated clinical efficacy of M.U.A. performed in a series of three consecutive procedures. The average numeric pain scale scores in the M.U.A. group decreased by 50%, and the average Roland-Morris questionnaire scores decreased by 51% compared to a controlled group.

Daniel West et al. reported in a 1998 study of 177 patients that 68.6% of patients out of work returned to unrestrictive work activities after a series of three consecutive M.U.A. procedures at 6 months post-M.U.A., that 58.4% of the M.U.A. patients receiving medications prior to the procedure required no specific medications post-procedure and finally, that 60.1% of the patients with lumbar pain resolved post-M.U.A. series of procedures.

Samuel Turek, M.D., Orthopedic Surgeon, reports in his text book, Principles and Applications of Orthopedics, that "good to excellent results can be expected with Manipulation Under Anesthesia."

Thomas Dorman, M.D., Orthopedist, recommends in his text book, Diagnostic Techniques in Orthopedic Medicine, Manipulation Under Anesthesia when the patient has failed at conservative in-office care.

Robert Mensor, M.D., Orthopedic Surgeon, conducted a large clinical trial of over 600 patients with EMG verified radiculopathy and found that 83% responded well to M.U.A.

These findings were verified by Donald Chrisman, M.D., Orthopedic Surgeon, reporting that 51% of patients with unrelieved symptoms after conservative care have good to excellent results even 3 years after M.U.A.

Bradford and Siehl reported on 723 M.U.A. patients, the largest trial conducted on M.U.A. procedures, and found that 71% had good results (normal activity and relatively symptom free) and that 25.3% had fair results (improvement, returned to relatively normal activity) and that flexibility, elasticity and range of motion can be restored to patients with chronic back pain.

Paul Kuo, M.D., professor of Orthopedic Surgery, reported his clinical investigation in 1986 of 517 patients treated with M.U.A., with 83.9% of the cases responding well.

Further research is ongoing. Well designed prospective controlled clinical trials are being conducted to evaluate the clinical and cost-effectiveness of M.U.A. procedures. It is important to note that to date there has been no clinical trial that demonstrates M.U.A. to be ineffective in an appropriately selected patient population. Clinical outcome assessments from these and previous studies will further delineate the parameters and the patient population within which M.U.A. can be most effective.

EXHIBIT E

Horizon℠

Horizon Blue Cross Blue Shield of New Jersey

Making Healthcare Work℠

June 14, 2011

GRIFFIN BINKO
9 SMITHVILLE ROAD
HEWITT NJ 07421

Dear Mr. Binko:

Re: Griffin Binko
ID: 3HZN08017100
Plan: ASC
Date(s) of Service: 7/8/10, 7/9/10 & 7/10/10
Physician: In Balance Health
Claim: 20101970218000 /multi

The provider appeal received from In Balance Health and medical documentation submitted for the above services has been reviewed by Horizon Sr. Medical Director, Stan E. Harris, M.D and an independent specialty matched consultant. After consideration of all the information provided, it has been determined that the denial is upheld.

This determination is based on the following:

"As indicated in the independent consultatns report: there is no good evidence based data to support the safety and long term efficacy of manipulation under anesthesia of the spine It is investigational. In addition, the clinical documentation does not support the medical necessity of the MUA of the pelvis."

CONSULTANTS RATIONALE:

In the appendicular skeleton, manipulation with the patient under anesthesia (MUA) may be performed as a treatment of arthrofibrosis, particularly of the shoulder (i.e., frozen shoulder) or knee. In the spine, manipulation under anesthesia may be performed as a closed treatment of vertebral fracture or dislocation. In the absence of vertebral fracture or dislocation, MUA, performed either with the patient sedated or under general anesthesia, is intended to overcome the conscious patient's protective reflex mechanism, which may limit the success of prior attempts of spinal manipulation or adjustment in the conscious patient. Manipulation under anesthesia (MUA) cannot be recommended at the present time. Existing studies are not high quality and the outcomes were not great plus the procedure is expensive and has risks. There is a need for high quality studies before recommending this. Literature only supports MUA for adhesive capsulitis or athrofibrosis of the knee. All other uses of this modality are investigational. Spinal manipulation under anesthesia (MUA) is considered investigational for the treatment of pain syndromes of musculoskeletal origin including, but not limited to spinal and pelvic pain.

Your plan only provides coverage for services deemed by us to be medically necessary and appropriate.

You have now exhausted all appeal levels available to you through our organization. However, if you are dissatisfied with this determination, your employer's contract may allow an additional appeal. Please contact the Benefits Administrator at your place of employment for further information.

Thank you for your cooperation.

Sincerely,

Clinical Analysis and Monitoring Unit.
Health Affairs

Enclosure

cc: IN-BALANCE HEALTH LLC
305 W GRAND AVENUE
MONTVALE NJ 07645

MONTVALE SURGICAL CENTER LLC
6 CHESTNUT RIDGE ROAD
MONTVALE NJ 07645

ADVANCED AMBULATORY ANESTHESIA
1176 HAMBURG TPKE
WAYNE NJ 07470

NEW JERSEY SPINAL CARE
JAMES WOLF DC
601 HAMBURG TPKE STE 101
WAYNE NJ 07470

Case: 20090301025

EXHIBIT F

Analysis
As of: Dec 21, 2012

ADVANCED REHABILITATION, LLC; IRBY SPINE CARE, PC; SHORE SPINE CENTER & PHYSICAL REHABILITATION, PC on behalf of themselves and others similarly situated, Appellants v. UNITEDHEALTHGROUP, INC.; UNITEDHEATHCARE; UNITEDHEALTHCARE INSURANCE COMPANY OF NEW YORK, INC.; UNITEDHEALTHCARE INSURANCE COMPANY; UNITEDHEALTHCARESERVICE, LLC; OXFORD HEALTH PLANS LLC; OXFORD HEALTH PLANS (NY), INC.; OXFORD HEALTH PLANS (NJ), INC.; OXFORD HEALTH INSURANCE, INC.

No. 11-4269

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

2012 U.S. App. LEXIS 20050

September 20, 2012, Submitted Under Third Circuit LAR 34.1(a)
September 25, 2012, Filed

NOTICE: NOT PRECEDENTIAL OPINION UNDER THIRD CIRCUIT INTERNAL OPERATING PROCEDURE RULE 5.7. SUCH OPINIONS ARE NOT REGARDED AS PRECEDENTS WHICH BIND THE COURT.

PLEASE REFER TO *FEDERAL RULES OF APPELLATE PROCEDURE RULE 32.1* GOVERNING THE CITATION TO UNPUBLISHED OPINIONS.

PRIOR HISTORY: [*1]

On Appeal from the United States District Court for the District of New Jersey. (D.C. No. 10-cv-00263). District Judge: Honorable Dennis M. Cavanaugh.
Advanced Rehab., LLC v. Unitedhealth Group, Inc., 2011 U.S. Dist. LEXIS 27710 (D.N.J., Mar. 17, 2011)

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant healthcare providers appealed orders by the United States District Court for the District of New Jersey that granted a motion from appellees, a healthcare company and its wholly owned subsidiaries, under *Fed. R. Civ. P. 12(b)(6)* to dismiss the providers' class action for failure to state a claim and that denied the providers subsequent motion for leave to file a second amended complaint.

OVERVIEW: The providers alleged that the company violated the Employee Retirement Income Security Act and state law by refusing to reimburse them for performing certain medical procedures. The health plans at issue only covered treatment that the company deemed medically necessary, and the use of manipulation under anesthesia (MUA) by the providers was not considered medically necessary by the company. The court held that the providers' implicit claim that MUA treatments were covered by the plans was merely a naked assertion that stopped short of the line between possibility and plausibility of entitlement to relief. Despite the fact that a medical necessity determination required an individualized assessment based on the specific needs of a patient, the providers alleged no facts to demonstrate that MUA procedures were medically necessary for the particular patients who received them. Similarly, the providers failed to allege that MUA procedures were both consistent with national medical standards and considered by medical literature to be safe and effective. The motion for leave to amend was properly denied because the addi-

tions were inadequate to have withstood another motion to dismiss.

OUTCOME: The orders were affirmed.

LexisNexis(R) Headnotes

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Failures to State Claims
Civil Procedure > Appeals > Standards of Review > De Novo Review
[HN1] An appellate court exercises plenary review over the grant of a motion to dismiss under *Fed. R. Civ. P. 12(b)(6)*.

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Failures to State Claims
Civil Procedure > Pleading & Practice > Pleadings > Complaints > Requirements
[HN2] A complaint may be dismissed for failure to state a claim upon which relief can be granted. *Fed. R. Civ. P. 12(b)(6)*. A court must accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief. Nevertheless, the plaintiff must provide more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. The plaintiff must allege enough facts to state a claim to relief that is plausible on its face. A court engages in a three-step analysis to determine the sufficiency of a complaint: First, the court must take note of the elements a plaintiff must plead to state a claim. Second, the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. Finally, where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

Pensions & Benefits Law > Employee Retirement Income Security Act (ERISA) > Judicial Review > Standards of Review > Abuse of Discretion
[HN3] In the context of the Employee Retirement Income Security Act, if, under health plans, a plan administrator retains discretion to determine whether procedures are medically necessary or experimental, an appellate court reviews these determinations for abuse of discretion. Consequently, an appellate court may overturn a plan administrator's decision only if it is without reason, unsupported by substantial evidence, or erroneous as a matter of law.

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Failures to State Claims
[HN4] Whether express or implied, conclusory allegations without more cannot unlock the doors of discovery. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Failures to State Claims
Civil Procedure > Summary Judgment > Motions for Summary Judgment > General Overview
[HN5] As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings. However, an exception to the general rule is that a document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court
Civil Procedure > Appeals > Standards of Review > Abuse of Discretion
Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Civil Procedure > Appeals > Standards of Review > De Novo Review
[HN6] An appellate court reviews a district court's denial of a motion to amend the complaint for abuse of discretion, but it reviews the district court's underlying legal determinations de novo and factual determinations for clear error.

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Failures to State Claims
Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court
[HN7] Futility is a valid reason to deny a motion for leave to file an amended complaint. Amendment is futile when the complaint, as amended, would fail to state a claim upon which relief could be granted.

COUNSEL: For ADVANCED REHAB, IRBY SPINE CARE, SHORE SPINE CENTER & PHYSICAL REHABILITATION, Plaintiff - Appellants: Lawrence P. Eagel, Esq., Bragar Wexler Eagel & Squire, New York, NY; Julie Lefkowitz, Esq., Hackensack, NJ.

For UNITED HEALTH GRP, UNITED HEATH CARE, UNITED HEALTHCARE INS CO, UNITED HEALTHCARE INS CO OF NEW YORK, UNITED HEALTHCARE SER, OXFORD HEALTH PLANS LLC, OXFORD HEALTHPLANS NEW YORK, OXFORD HEALTHPLANS NEW JERSEY, OXFORD HEALTH INS, Defendant - Appellees: Brian D. Boyle, Esq., Christopher D. Catalano, Esq., Jonathan D. Hacker, Esq., O'Melveny & Myers, Washington, DC; Thomas R. Curtin, Esq., George C. Jones, Esq., Graham Curtin, Morristown, NJ; Andrew J. Frackman, Esq., Anton Metlitsky, Esq., O'Melveny & Myers, New York, NY.

JUDGES: Before: SLOVITER, RENDELL and HARDIMAN, Circuit Judges.

OPINION BY: HARDIMAN

OPINION

OPINION OF THE COURT

HARDIMAN, *Circuit Judge.*

Advanced Rehabilitation, LLC, Irby Spine Care, PC, and Shore Spine Center & Physical Therapy, PC (collectively, Plaintiffs), filed a class action against UnitedHealth Group, Inc., and its wholly owned [*2] subsidiaries operating in New York and New Jersey (collectively, UnitedHealth). Plaintiffs allege that UnitedHealth violated the Employee Retirement Income Security Act (ERISA) and state law by refusing to reimburse them for performing certain medical procedures. The United States District Court for the District of New Jersey granted UnitedHealth's motion to dismiss for failure to state a claim and denied Plaintiffs' subsequent motion seeking both reconsideration and leave to file a second amended complaint. For the reasons that follow, we will affirm.

I

Because we write for the parties, we recount only the essential facts and procedural history.

Plaintiffs were healthcare providers who did not participate in UnitedHealth's provider network. This meant they were free to set their own rates, for which their patients could seek reimbursement pursuant to their own UnitedHealth plans. As a matter of course, however, patients assigned their insurance benefits to Plaintiffs, who then were entitled to seek reimbursement from UnitedHealth.

Four health plans are at issue in this case: the Empire Plan, the Verizon Choices plan, the Port Authority Plan, and the Freedom Plan. Under all four plans, [*3] UnitedHealth was to make an initial determination as to whether a procedure was covered. If coverage was denied, the insured could appeal that determination either internally to UnitedHealth or to a state-certified entity before filing suit in court. [1]

1 The Verizon and Freedom Plans were governed by ERISA, while the Empire and the Port Authority Plans were not. ERISA provides for a beneficiary to sue for "benefits due to him under the terms" of an ERISA-governed health plan. *29 U.S.C. § 1132(a).*

All four plans covered only treatment that UnitedHealth deemed "medically necessary." While the meaning of "medical necessity" differed slightly under each plan, it generally required treatment to be (1) necessary to meet the patient's needs, (2) not solely for the patient's convenience, (3) the most appropriate level of service that could safely be supplied, (4) supported by national medical standards, and (5) considered by medical literature to be a safe and effective method of treating the patient's symptoms. The plans also excluded procedures that UnitedHealth considered experimental, investigational, or unproven.

The amended complaint at issue on appeal alleges that each Plaintiff performed [*4] manipulation under anesthesia (MUA), a type of manual therapy intended to improve articular and soft tissue movement. For joints lacking a complete range of motion, a specially trained physician and an anesthesiologist work together to break up scar tissue around the joint.

According to the complaint, MUA procedures have been listed for more than thirty years under a Category I CPT code in the Codebook of Reimbursable Procedures published by the American Medical Association (AMA). Plaintiffs claim that for a procedure to be listed under that code, the AMA must determine that the procedure: (1) "has received approval from the Food and Drug Administration;" (2) "is a distinct service performed by many physicians . . . across the United States;" and (3) "is well-established and documented in the peer-reviewed literature in the United States."

Plaintiffs allege that UnitedHealth routinely denies reimbursement for MUA because it considers the treatment not "medically necessary." The complaint cites four representative cases in which UnitedHealth denied reimbursement for MUA procedures performed on patients who were covered by a UnitedHealth plan. In each case, one of the Plaintiffs pursued [*5] several levels of appeal but was informed that UnitedHealth was denying coverage. After exhausting their administrative appeals, Plaintiffs filed suit in the District Court.

Plaintiffs' complaint alleged breach of contract and breach of fiduciary duty under both ERISA and state

law. UnitedHealth moved to dismiss the complaint for failure to state a claim, and Plaintiffs filed an amended complaint. UnitedHealth again moved to dismiss.

Although the case had not reached discovery, the District Court requested copies of UnitedHealth's letters denying coverage for MUA procedures. UnitedHealth complied with that request, and Plaintiffs submitted related documents. The letters demonstrated that Plaintiffs had sought coverage for MUA treatment and that their claims had been denied based on UnitedHealth's determination that MUA was either "experimental" or not "medically necessary."

The District Court dismissed the amended complaint. Plaintiffs then moved both for reconsideration and for leave to file a second amended complaint, but their motion was denied. Plaintiffs filed a timely notice of appeal.

II [2]

> 2 The District Court had jurisdiction pursuant to *28 U.S.C. §§ 1331* and *1367*. We have jurisdiction [*6] under *28 U.S.C. § 1291*. [HN1] We exercise plenary review over the grant of a motion to dismiss under *Federal Rule of Civil Procedure 12(b)(6)*. *Burtch v. Milberg Factors, Inc., 662 F.3d 212, 220 (3d Cir. 2011)*.

[HN2] A complaint may be dismissed for "failure to state a claim upon which relief can be granted." *Fed. R. Civ. P. 12(b)(6)*. The court must "'accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009)* (quoting *Phillips v. Cnty. of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008)*). Nevertheless, the plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)* (citation and internal quotation marks omitted). The plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Id. at 570*.

We engage in a three-step analysis to determine the sufficiency of a complaint:

> First, the court must "tak[e] note of the elements a plaintiff [*7] must plead to state a claim." Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Finally, "where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief."

Burtch, 662 F.3d at 221 (quoting *Santiago v. Warminster Twp., 629 F.3d 121, 130 (3d Cir. 2010)*).

III

We begin with Plaintiffs' challenge to the District Court's dismissal of their amended complaint. Plaintiffs argue that the complaint stated a plausible entitlement to relief. We disagree.

[HN3] Under the representative plans, UnitedHealth retained discretion to determine whether procedures were "medically necessary" or "experimental." We review these determinations for abuse of discretion. *Viera v. Life Ins. Co. of N. Am., 642 F.3d 407, 413 (3d Cir. 2011)*. Consequently, we may overturn a plan administrator's decision only "if it is 'without reason, unsupported by substantial evidence or erroneous as a matter of law.'" *Miller v. Am. Airlines, Inc., 632 F.3d 837, 845 (3d Cir. 2011)* (quoting *Abnathya v. Hoffmann-La Roche, Inc., 2 F.3d 40, 45 (3d Cir. 1993)*).

In [*8] analyzing whether Plaintiffs have pleaded sufficient facts to demonstrate that UnitedHealth's coverage determinations plausibly amounted to an abuse of discretion, we first note that the amended complaint does not explicitly allege that MUA procedures were "medically necessary" and not "experimental." According to Plaintiffs, however, their complaint "rest[s] on the premise that the MUA treatments fit th[e] criteria" of "medical necessity" because "otherwise, the procedures would not have been covered by the plans." [3] Plaintiffs' Br. 19. In our view, Plaintiffs' implicit claim that MUA treatments are covered by UnitedHealth plans is merely a "naked assertion" that stops "short of the line between possibility and plausibility of 'entitlement to relief.'" *Twombly, 550 U.S. at 557* (citing *DM Research, Inc. v. Coll. of Am. Pathologists, 170 F.3d 53, 56 (1st Cir. 1999)*).

> 3 As we discuss below, even if Plaintiffs had asserted that the MUA procedures were "medically necessary," that would have been insufficient because, [HN4] whether express or implied, conclusory allegations without more cannot "unlock the doors of discovery." *Ashcroft v. Iqbal, 556 U.S. 662, 678-79, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009)*. "Threadbare recitals of the [*9] elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id. at 678* (citing *Twombly, 550 U.S. at 555*).

Nor does the amended complaint make specific factual allegations from which we can infer that MUA procedures were covered. Despite the fact that a "medical necessity" determination requires an individualized assessment based on the specific needs of a patient, Plaintiffs have alleged no facts to demonstrate that MUA procedures were "medically necessary" for the particular patients who received them. Plaintiffs have not even alleged that MUA procedures were beneficial to their patients, let alone necessary to meet their needs. The amended complaint likewise contains no facts suggesting that MUA treatment was the most appropriate level of service that could safely be supplied in the given circumstances.

Similarly, Plaintiffs have failed to allege that MUA procedures were both consistent with national medical standards and considered by medical literature to be safe and effective. Plaintiffs cite only the AMA's listing of MUA procedures under a Category 1 CPT code, which Plaintiffs assert "may not be dispositive of the appropriateness of MUA procedures here, [*10] [but] certainly, at a minimum, lends weight to the plausibility of Plaintiffs' claims." Plaintiffs' Br. 18. But a mere CPT code is not enough to establish a plausible entitlement to relief. Indeed, in its Introduction to the Codebook, the AMA warns that "[i]nclusion in the . . . codebook does not represent endorsement . . . of any particular diagnostic or therapeutic procedure." [4] The Introduction also states that "inclusion or exclusion of a procedure does not imply any health insurance coverage or reimbursement policy." And even if a CPT code from just one organization were enough to suggest that MUA treatment is consistent with national standards, Plaintiffs have not demonstrated that such treatment plausibly would be considered safe and effective for treating the individual patients in this case. Without such an individualized assessment, the complaint is fatally flawed.

4 Plaintiffs contend that the District Court erred by considering facts like these, which fall outside the complaint, without converting UnitedHealth's motion into a motion for summary judgment. This argument is unavailing. [HN5] "As a general matter, a district court ruling on a motion to dismiss may not consider matters [*11] extraneous to the pleadings." *In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997)* (citing *Angelastro v. Prudential-Bache Sec., Inc., 764 F.2d 939, 944 (3d Cir. 1985)*). "However, an exception to the general rule is that a 'document *integral to or explicitly relied* upon in the complaint' may be considered 'without converting the motion [to dismiss] into one for summary judgment.'" *Id.* (quoting *Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1220 (1st Cir. 1996)*). In this case, the District Court properly considered both the UnitedHealth plans and the AMA's Codebook because they were "integral to" and "explicitly relied upon" in the complaint. *Cf. DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442, 444 n.2 (3d Cir. 2003)* (permitting consideration of plan documents where "DiFelice's reference to 'medical necessity' [was] clearly derived from the terms of the Plan"). And though the District Court requested UnitedHealth's letters denying coverage, it did not rely on any substantive facts gleaned from those documents.

Finally, Plaintiffs argue that facts regarding individualized treatment are unnecessary in this case because UnitedHealth maintained "a company-wide practice [*12] by which all in-house appeals of the denial of claims for MUA's [were] routinely rejected without regard to the merits of the particular individual claims." Even assuming the existence of such a policy, however, Plaintiffs' allegations fall well short of plausibly showing that the policy was arbitrary and capricious. Indeed, if MUA procedures were either "experimental" or not "medically necessary" as defined by the representative plans, routinely denying coverage for such procedures would have been consistent with the terms of those plans.

For all of these reasons, the District Court did not err when it granted UnitedHealth's motion to dismiss the amended complaint.

IV

We now turn to Plaintiffs' argument that the District Court erred when it denied their motion for leave to amend. [HN6] "We review the District Court's denial of a . . . motion to amend the complaint for abuse of discretion, but we review the District Court's underlying legal determinations *de novo* and factual determinations for clear error." *Burtch, 662 F.3d at 220* (citations omitted).

The District Court did not abuse its discretion in denying Plaintiffs' motion because the proposed complaint would not have demonstrated a plausible [*13] entitlement to relief. *Id. at 231* (indicating that [HN7] futility is a valid reason to deny a motion for leave to file an amended complaint). Amendment is futile when the "'complaint, as amended, would fail to state a claim upon which relief could be granted.'" *Great W. Mining & Mineral Co. v. Fox Rothschild LLP, 615 F.3d 159, 175 (3d Cir. 2010)*(quoting *In re Merck & Co. Sec., Derivative, & ERISA Litig., 493 F.3d 393, 400 (3d Cir. 2007)*).

In relevant part, the proposed complaint added only conclusory allegations that MUA was "medically necessary," as well as an isolated claim that one medical journal article from 1999 had found MUA to be "safe and

efficacious" in certain contexts. These additions were inadequate to have withstood another motion from UnitedHealth to dismiss the complaint. Consequently, the District Court did not abuse its discretion when it denied Plaintiffs leave to file a second amended complaint.

V

For the reasons stated, we will affirm the District Court's orders granting UnitedHealth's motion to dismiss and denying Plaintiffs' motion.